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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay, Kaplun & Marcin, LLP

DATE : June 23, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/768,629
for *Stacked Membrane for Pressure Actuated Valve*
Inventor(s): Weaver et al.
Our Ref.: 10142/00901

NUMBER OF PAGES INCLUDING COVER : 15

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Attorney Docket No. 10142/00901(03-326)

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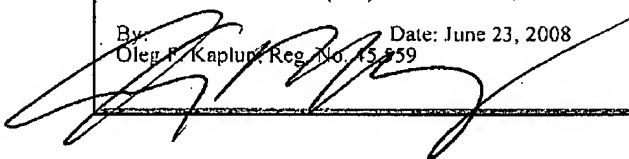
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Inventor(s) : Weaver et al.
Serial No. : 10/768,629
Filing Date : January 29, 2004
For : Stacked Membrane For Pressure Actuated Valve
Group Art Unit : 3767
Confirmation No. : 6763
Examiner : Emily L. Wachtel

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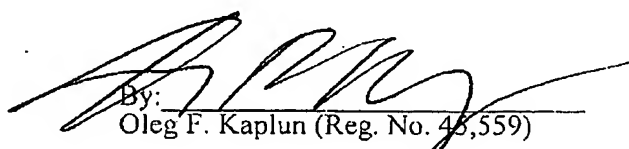
By:  Date: June 23, 2008
Oleg F. Kaplun, Reg. No. 45,559

TRANSMITTAL

In support of the Notice of Appeal filed on May 22, 2008, transmitted herewith please find an Appeal Brief for filing in the above-identified application. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of \$510.00 (PTO-Form 2038 is enclosed herewith) for the filing fees. The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: June 23, 2008


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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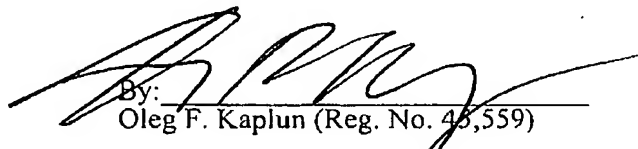
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PATENT

Attorney Docket No.: 10142 - 00901

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Weaver et al.

Serial No.: 10/768,629

Filed: January 29, 2004

For: STACKED MEMBRANE
FOR PRESSURE ACTUATED
VALVE

Group Art Unit: 3767

Examiner: E. Wachtel

Board of Patent Appeals and
InterferencesMail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed May 22, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants presents an Appeal Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-7 in the Final Office Action dated March 17, 2008. The appealed claims are set forth in the attached Claims Appendix.

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Group Art Unit: 3767
Attorney Docket No.: 10123 - 00901

1. **Real Party in Interest**

This application is assigned to NAMIC/VA, Inc., the real party in interest.

2. **Related Appeals and Interferences**

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. **Status of the Claims**

Claims 1-7 have been rejected in the final Office Action, and are the subject of the present appeal. Claims 8-28 have been canceled..

4. **Status of Amendments**

All amendments submitted by the Appellants have been entered.

5. **Summary of Claimed Subject Matter**

The present invention, as recited in independent claim 1, is directed to a pressure activated valve 20 for medical applications. (Figs. 1A-1C; specification at paragraph [0018]). Valve 20 includes a housing 30 having a lumen extending therethrough from a proximal end to a distal end thereof. (Id.). The valve also includes a flow control membrane 32 extending across the lumen to control flow therethrough, the flow control membrane 32 including a mounting portion at which the flow control membrane 32 is coupled to the housing 30 and a lumen occluding portion having a slit extending therethrough. (Figures 1A-1C; specification at [0006] and [0018]). When the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented

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to an open configuration in which flow is permitted, and a thickness of the mounting portion is greater than a thickness of the lumen occluding portion. (Figures 1A-1C; specification at [0006] and [0007]. Further, the mounting portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed. (Figure 4; specification at [0031]).

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,205,834 to Moorehead et al. Applicants have amended claim 1 to recite that "the mounting portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed." Support for this amendment is found at least in Figure 4 and its associated description in the specification. The Examiner has likened the recited mounting and lumen occluding portions to discs 120 and 124. Nevertheless, as is plainly illustrated in Figure 5 of Moorehead, disc 120 covers a majority, not minority, of the surface area of the surface in disc 124 where slit 146 is disposed. Thus, in view of this discussion, Moorehead does not anticipate claim 1.

Claims 2 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moorehead. Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moorehead in view of United States Patent No. 5,944,698 to Fischer et al. Since Fischer does not overcome the deficiencies noted above with respect to Moorehead, Applicants submit that claims 2 and 4-7 are patentable for at least the same reasons given above.

6. **Grounds of Rejection to be Reviewed on Appeal**

- I. Whether claims 1-4 are obvious under 35 U.S.C. § 103(a) in view of United States Patent No. 5,205,834 to Moorehead et al. and United States Patent No. 3,811,466 to Ohringer.
- II. Whether claims 5-7 are obvious under 35 U.S.C. § 103(a) in view of Moorehead et al, Ohringer, and United States Patent No. 5,944,698 to

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Fischer et al.

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7. Argument

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moorehead in view of Ohringer. The Examiner relies on Ohringer to show the limitation "wherein the mounting portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed." Applicants respectfully disagree. First, since Ohringer does not state that its drawings are drawn to scale, the proportions of the drawings cannot be relied on as accurate. See MPEP § 2125. Therefore, even if a mounting flange 13 appears to cover a minority of a surface of a diaphragm 17, that appearance cannot be regarded as evidence of the actual proportions of these elements. Second, even if the drawings accurately represented the relative proportions of the flange 13 and the diaphragm 17, the flange 13 does not cover a minority of the surface area of the diaphragm 17. Applicants have calculated the area of the flange 13 in Figure 2 to be about 0.687 square inches (area of outer disk minus area of hole), and the area of the diaphragm 17 to be about 0.994 square inches. Thus, Figure 2 shows that the flange 13 covers a majority of the area of diaphragm 17. Accordingly, withdrawal of this rejection is requested.

In the Advisory Action, the Examiner does not dispute that flange 13, as illustrated in the drawings, occupies a majority of the surface area of diaphragm 17. Instead, the Examiner states that the "device of Ohringer suggests the recited limitation in Figure 2 regarding diaphragm 17. Further, Ohringer explicitly teaches varying the diameters of the openings surrounding the slit in order to control the flow...and that the length of the slit would be equal to or greater than the diameter...Thereby, when increasing the size of the slit, and increasing the diameters of the openings surrounding the slit to control the flow the mounting portion would cover a minority of the surface area." Appellants respectfully disagree with this argument. The Examiner relies on

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lines 50-51 of column 2 of Ohringer to assert that diameter d3 of plate 19 can be varied. The Examiner further relies on lines 40-41 of column 2 to state that "the length of the slit would be equal to or greater than the diameter." But the diameter in the sentence just quoted is diameter d1 of flange 13. ("The length L1 is preferably the same as, or longer than, the inside diameter d1 of flange 13."). Even though the words of the Examiner suggest that the diameter whose length is compared to the length of the slit is d3, that is not the case since the length is compared by Ohringer to diameter d1. Thus, the passage at lines 50-51 is not relevant to the passage at lines 40-41 of column 2.

The Examiner has likened flange 13 to the recited mounting portion, and has pointed to the passage at lines 40-41 of column 2 to support the contention that it would have been obvious to vary the diameter d1 so that flange occupies only a minority of the surface area of diaphragm 17. To the contrary, the importance attached by Ohringer on having a slit length L1 that is longer than diameter d1 demonstrates that one of ordinary skill in the art would want to keep the diameter d1 small relative to the slit length L1, which would result in a flange 13 that occupies a majority of the diaphragm surface area. Moreover, even though Ohringer states that "L1 may be made of lesser length and will provide a more restricted flow than if L1 were the same as or greater than diameter d1," the option to make L1 smaller than d1 does not in and of itself entail adjusting the size of d1 so that it occupies a minority surface area of diaphragm 17. In fact, Ohringer indicates that in adjusting the ratio of the flange diameter d1 to slit length L1, most of the adjustment in achieving a desired ratio would need to be made to the slit length L1. This is because Ohringer emphasizes that the size of d1 is constrained by the size of the pipes flange 13 is to cooperate with. Specifically, Ohringer states that "[f]langes 13 and 15 normally have inside diameters d1 and d2 that are about the same as the inside diameter of the piping to which they are connected." Column 2, lines 28-31. Thus, one of ordinary skill in the art would find little reason

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to adjust the flange 13 in a manner that would meet the claim. Although Ohringer goes on to mention that "these openings [i.e., including d1 of flange 13] may be larger or smaller depending upon special design considerations," such a statement is too speculative to support modifying Ohringer to meet the claim since Ohringer does not explain what "special design considerations" mean. In fact, in order to read this speculative statement consistently with the other statement enjoining one of ordinary skill in the art to keep the size d1 compatible with the pipes it is to work with, the "special design considerations" should be viewed as teaching only those minor adjustments that would still maintain the compatibility of flange 13 with the pipes it was originally intended to work with. This reading would thus rule out any adjustments to d1 significant enough to render flange 13 unworkable with such pipes. Since the "special design considerations" thus are not to be read as vitiating the requirement of compatibility with the piping mentioned above, one of ordinary skill in the art would have no reason to adjust the size d1 to such an extent that it would shift from covering a majority of diaphragm 17 to a minority.

Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moorehead in view of U.S. Patent No. 5,944,698 to Fischer et al. Since Fischer does not overcome the deficiencies noted above with respect to Moorehead, Applicants submit that claims 5-7 are patentable for at least the same reasons given above.

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8. Conclusion

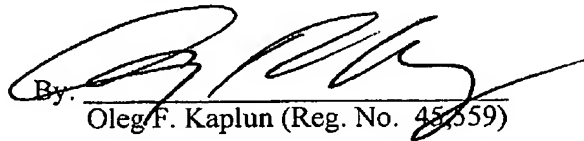
For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner.

Respectfully submitted,

Date:

6/23/08

By:



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Serial No.: 10/768,629
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1. (Previously Presented) A pressure activated valve for medical applications comprising: a housing having a lumen extending therethrough from a proximal end to a distal end thereof; and a flow control membrane extending across the lumen to control flow therethrough, the flow control membrane including a mounting portion at which the flow control membrane is coupled to the housing and a lumen occluding portion having a slit extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted and wherein a thickness of the mounting portion is greater than a thickness of the lumen occluding portion, wherein the mounting portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed.
2. (Original) The pressure activated valve according to claim 1, wherein the flow control membrane comprises a first membrane bonded to an annular base member wherein an area of the base membrane substantially corresponds to that of the mounting portion and wherein the slit extends through the first membrane.
3. (Original) The pressure activated valve according to claim 1, further comprising a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion.
4. (Original) The pressure activated valve according to claim 2, further comprising a layer of adhesive disposed between the first membrane and the base membrane.

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5. (Original) The pressure activated valve according to claim 2, wherein the first membrane has a thickness of no more than 0.035 in.
6. (Original) The pressure activated valve according to claim 1, wherein a thickness of the lumen occluding portion is between 0.005 and 0.100 inches.
7. (Original) The pressure activated valve according to claim 1, wherein a thickness of the mounting portion is between 1 and 20 times a thickness of the lumen occluding portion.
8. - 28. (Canceled)

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EVIDENCE APPENDIX

No evidence has been submitted herewith or is relied upon in the present appeal.

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RELATED PROCEEDINGS APPENDIX

There are no related proceedings and/or decisions which relate to the present appeal.